OFFICE OF POLLUTION PREVENTION AND TOXIC'S (OPPT'S) DECISION LOGIC FOR SELECTION OF RESPIRATORS FOR PMN SUBSTANCES



HALF MASK AIR PURIFYING RESPIRATOR



FULL FACE AIR PURIFYING RESPIRATOR



POWERED AIR PURIFYING RESPIRATOR WITH HOOD



FULL FACE PRESSURE DEMAND SUPPLIED AIR RESPIRATOR

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Office of Pollution Prevention and Toxic's (OPPT's) Decision Logic for Selection of Respirators for PMN Substances (01-28-10)

1.1 Purpose

This document provides guidance on the selection of the appropriate respirator in cases where EPA risk assessors have determined that there is a concern for occupational exposure to Pre-Manufacture Notice (PMN) substances via inhalation. The guidance provided in this document will be used by EPA to determine which respirators to require in Toxic Substances Control Act (TSCA) Section 5(e) Consent Orders, Significant New Use Rules (SNURs), Low Volume Exemptions, and other regulatory instruments.

In order to provide protection at the indicated Assigned Protection Factor (APF) level, respirators must be used within a complete respiratory protection program such as the one required by the Occupational Safety and Health Administration (OSHA) in its Respiratory Protection Standard (29 CFR 1910.134). In addition to other requirements, the OSHA standard also requires that all selected respirators be NIOSH-certified.

1.2 Introduction

Effective control of chemical hazards in the workplace is critical to keep employee exposures to harmful substances below levels of concern. The industrial hygiene hierarchy of controls recommends that engineering controls, such as enclosed processes or local exhaust ventilation, be used to control workplace chemical hazards. If engineering controls are not feasible or are unable to reduce chemical concentrations below occupational exposure limits, administrative controls such as housekeeping, work schedules, and work practices should be used to minimize exposures. Finally, personal protective equipment such as respirators may be required to ensure that employee inhalation exposures during certain tasks remain below levels of concern. While respirators are an important component of workplace health and protection, they should be used only when other controls are not possible or do not provide adequate protection. The EPA typically requires respirator use in consent orders because it is difficult to evaluate specific engineering and administrative controls on a site-by-site basis. Approaches such as the new chemical exposure limit (NCEL) provisions also encourage the use of engineering controls over respirators.

1.3 How to Use This Document

The body of this document contains the respirator selection procedures and tables that list respirator types that are appropriate for use according to the estimated assigned protection factors (APFs). It also contains a flowchart to assist the user in the respirator selection process. In addition, several appendices supplement the decision logic by providing other relevant information. These appendices include:

Appendix A: Risk Assessment and Calculation of the Hazard Ratio

Appendix B: Additional Considerations for Selection and Use of Respirators

Appendix C: Fit Testing

Appendix D: The Role of OSHA and NIOSH in Respiratory Protection

Appendix E. NIOSH Certification Requirements for Particulate Respirators

Appendix F: Glossary

Appendix G: References

1.4 Respirator Selection Procedures

To the extent possible, determine whether there are any limitations within the work environment that would preclude respirator use. If the environment in which the respirator will be used is suspected to be Immediately Dangerous to Life and Health (IDLH) or is oxygen deficient (note: OSHA considers an oxygen deficient atmosphere to be IDLH), none of the respirators listed in the tables will be acceptable. For these situations, only pressure-demand or other positive pressure self-contained breathing apparatus (SCBA) or pressure-demand or other positive pressure supplied air respirator (SAR) with auxiliary SCBA should be used according to the requirements in the OSHA Respiratory Protection Standard (29 CFR 1910.134).

Use the following steps to select an appropriate respirator group for the substance and conditions under consideration. A flowchart of the decision logic for respirator selection immediately follows these respirator selection procedures.

- 1. From the program manager or the risk assessor, obtain the hazard ratio for the PMN substance. [The Risk Assessment Division (RAD) will make a determination of the fold factor/hazard ratio either by calculating a margin of exposure ratio (See Appendix A for more information), by using a New Chemical Exposure Limit (NCEL) for the substance, or by other methods acceptable to RAD.] The hazard ratio value will be used as an indicator to estimate the minimum APF required for respirator selection for that substance.
- 2. Determine whether or not a respirator is required. If the calculated value of the hazard ratio is above one, a respirator is required. If the hazard ratio value is over 10,000, this document cannot be used for respirator selection, as the value exceeds the APF range in this document. Contact the CEB Industrial Hygienist for assistance in this situation.
- 4. From the Initial Review and Engineering Report (IRER), obtain the following information: 1) the physical form of the substance to which the worker is exposed (e.g., particulate, gas/vapor, or combination of gas/vapor and particulate) and 2) estimated worker exposure levels and the potential for irritation or toxicity to mucous membranes, eyes, and/or skin. For assistance in determining the applicable physical form, particularly if the physical form changes during the process or use, contact the engineer assigned to the case.
- 5. Use the known physical form of the substance from the IRER to determine which class of respirator is required. The available classes include:
 - I. Particulate/Aerosol (solids or liquid droplets suspended in a gas; e.g., dust, fume, mist),
 - II. Gas/vapor (all substances in the gas form), or
 - III. Combination Particulate and Gas/Vapor (gas and liquid/solid physical forms are both present, e.g., particulates and acid gases or organic vapors; a good example is paint spray mist, which contains both liquid droplets and vapor).
- 6. Once the appropriate class of respirator (I, II, or III) is determined, use the calculated hazard ratio value from Step 1 to select the respirator group from Tables I, II, and III. Only respirators that have APFs equal to or greater than the hazard ratio should be selected.

As an example, if the hazard ratio value for a particulate substance is 35, then the respirator selected should have an APF that meets or exceeds this hazard ratio value. In this case, since the substance is a particulate, the appropriate respirators will be listed in Table I. In the "Hazard Ratio Range" column, locate the hazard ratio range in which your hazard ratio falls, which, in this case, is the 26-50 range. An APF of 50 is

indicated next to this range under the "Assigned Protection Factor" and represents the appropriate APF value that should be selected. Select all respirators under the "Types of Respirators", which meet the APF of 50.

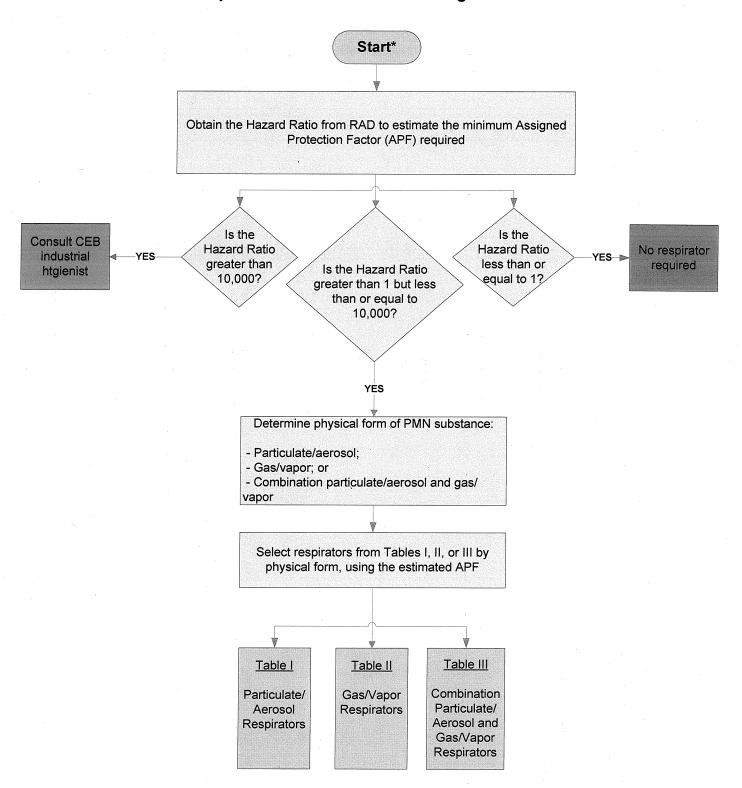
If a significant exposure concern (i.e., toxicity or irritation) exists for the mucous membranes, eyes, or skin, select only those respirators in the group which will provide full-face protection, i.e., a respirator equipped with a full facepiece, helmet, or hood.

A complete listing of all available groups in Tables I, II, and III follows the respirator flowchart below. Note that this decision logic is limited to identifying classes of acceptable respirators rather than individual respirator models.

The applicable list of respirators from the group should then be included in the 5(e) Consent Order, SNUR, or other EPA regulatory instrument.

7. Considerations like service life needs, the need for mobility, compatibility with other protective equipment, and respirator durability needs, etc. (see Appendix B for additional information) are also important for determining respirator selection, but must usually be considered by the submitter rather than by EPA because of the variability that exists between individual work sites.

Respirator Selection Decision Logic Flowchart



*If the environment in which the respirator will be used is suspected to be Immediately Dangerous to Life and Health (IDLH) or is oxygen deficient, none of the respirators listed in the Respirator Selection Logic tables will be acceptable [Note: OSHA considers an oxygen deficient atmosphere to be IDLH.]

TABLE I. PARTICULATE/AEROSOL RESPIRATORS

Fold Factor/ Hazard Ratio Range	Assigned Protection Factor (APF)	Type of Respirator
2 to10	10	Any NIOSH-certified air-purifying elastomeric half-mask respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters. [If a concern exists for eye/skin exposure from the chemical, this option should not be included in the 5(e) Order or EPA action.]
		Any appropriate NIOSH-certified N100 (if oil aerosols absent), R100, or P100 filtering facepiece respirator. [Note: for filtering facepieces, an APF of 10 can only be achieved if the respirator is qualitatively or quantitatively fit tested on individual workers. If a concern exists for eye/skin exposure from the chemical, this option should not be included in the 5(e) Order or EPA action.]
		Any NIOSH-certified air-purifying full facepiece respirator equipped with N100 (if oil aerosols absent), R100, or P100 filters. [provides eye/face protection]
		Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a half-mask. [If a concern exists for eye/skin exposure from the chemical, this option should not be included in the 5(e) Order or EPA action.]
		Any NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a half mask. [If a concern exists for eye/skin exposure from the chemical, this option should not be included in the 5(e) Order or EPA action.]
11 to 25	25	Any NIOSH-certified powered air-purifying respirator equipped with a hood or helmet and HEPA filters. [provides eye/face protection].
		Any NIOSH-certified powered air-purifying respirator equipped with a loose fitting facepiece and HEPA filters. [provides eye/face protection]
		Any NIOSH-certified continuous flow supplied-air respirator equipped with a hood or helmet. [provides eye/face protection].
		Any NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece. [provides eye/face protection]
26 to 50		Any NIOSH-certified air-purifying full facepiece respirator equipped with N100 (if oil aerosols absent), R-100, or P-100 filter(s). [provides eye/face protection]
		Any NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (half or full facepiece) and equipped with HEPA filters. [full facepiece provides eye/face protection]

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Fold Factor/ Hazard Ratio Range	Assigned Protection Factor (APF)	Type of Respirator
y i		Any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a half-mask. [If a concern exists for eye/skin exposure from the chemical, this option should not be included in the 5(e) Order or EPA action.]
		Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a full facepiece. [provides eye/face protection]
		Any NIOSH-certified continuous flow supplied-air respirator equipped with a tight-fitting facepiece (half or full facepiece). [full facepiece provides eye/face protection]
		Any NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a hood or helmet or a full facepiece. [provides eye/face protection]
51 to 1,000	1,000	Any NIOSH-certified powered air purifying full facepiece respirator equipped with HEPA filters. [provides eye/face protection].
		Any NIOSH-certified powered air-purifying respirator equipped with a hood or helmet* and N100 (if oil aerosols absent), R100, or P100 filters with evidence demonstrating protection level of 1,000 or greater. [provides eye/face protection]. [See important note below].*
		Any NIOSH-certified continuous flow supplied-air respirator equipped with a full facepiece. [provides eye/face protection].
		Any NIOSH-certified continuous flow supplied-air respirator equipped with a hood or helmet <i>with evidence demonstrating protection level of 1,000 or greater</i> . [provides eye/face protection]. [See important note below].*
		Any NIOSH-certified pressure-demand supplied-air respirator equipped with a full facepiece. [provides eye/face protection]
1001 to 10,000	10,000	Any NIOSH-certified pressure-demand or other positive-pressure mode (e.g., open/closed circuit) self-contained breathing apparatus (SCBA) equipped with a hood or helmet or a full facepiece. [provides eye/face protection]

^{*} OSHA has assigned APFs of 1000 for certain types of hoods and helmets with powered air purifying respirators (PAPRs) or supplied air respirators (SARs) where the manufacturer can demonstrate adequate air flows to maintain positive pressure inside the hood or helmet in normal working conditions. However, the employer must have evidence provided by the respirator manufacturer that the testing of these respirators demonstrates performance at a level of protection of 1,000 or greater to receive an APF of 1,000. This level of performance can best be demonstrated by performing a Workplace Protection Factor (WPF) or Simulated Workplace Protection Factor (SWPF) study or equivalent testing. Without testing data that demonstrates a level of protection of 1,000 or greater, all PAPRs and SARs with helmets/hoods are to be treated as loose-fitting facepiece respirators, and receive an APF of 25.

TABLE II. GAS/VAPOR RESPIRATORS

Fold Factor/ Hazard Ratio Range	Assigned Protection Factor (APF)	Type of Respirator
2-10	10	If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:
		Any NIOSH-certified air-purifying half mask respirator equipped with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges. [If a concern exists for eye/skin exposure from the chemical, the half-mask option should not be included in the 5(e) Order or EPA action.]
		Any NIOSH-certified powered air-purifying respirator with a hood or helmet and with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges [provides eye/face protection]
		Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a half-mask. [If a concern exists for eye/skin exposure from the chemical, the half-mask option should not be included in the 5(e) Order or EPA action.]
		Any NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece, hood, or helmet. [provides eye/face protection]
		Any NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a half-mask. [If a concern exists for eye/skin exposure from the chemical, the half-mask option should not be included in the 5(e) Order or EPA action.]
		If No Cartridge Service Life Testing has been Conducted:
		Any NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece, hood, or helmet. [provides eye/face protection]
		Any NIOSH-certified negative pressure (demand) supplied-air respirator (half-mask or full facepiece). [If a concern exists for eye/skin exposure from the chemical, the half-mask option should not be included in the 5(e) Order or EPA action.]
		Any NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a half-mask. [If a concern exists for eye/skin exposure from the chemical, the half-mask option should not be included in the 5(e) Order or EPA action.]
11-25		If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:
		Any NIOSH-certified powered air-purifying respirator with a hood or helmet equipped with appropriate gas/vapor (acid gas, organic vapor, or

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Fold Factor/ Hazard Ratio Range	Assigned Protection Factor	Type of Respirator
Kange	(APF)	
		substance specific) cartridges. [provides eye/face protection]
		Any NIOSH-certified powered air-purifying respirator equipped with a loose fitting facepiece with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges. [provides eye/face protection]
		Any NIOSH-certified continuous flow supplied-air respirator equipped with a hood or helmet. [provides eye/face protection]
		Any NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece. [provides eye/face protection]
		If No Cartridge Service Life Testing has been Conducted:
		Any NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece, hood, or helmet. [provides eye/face protection]
		Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a full facepiece. [provides eye/face protection]
26-50	50	If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA: Any NIOSH-certified air-purifying full facepiece respirator equipped with appropriate gas/vapor cartridges or canisters (acid gas, organic vapor, or substance specific). [provides eye/face protection]
		Any NIOSH-certified powered air-purifying respirator equipped with a tight-fitting facepiece (half or full facepiece) and appropriate gas/vapor cartridges or canisters (acid gas, organic vapor, or substance specific). [provides eye/face protection]
		Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a full facepiece. [provides eye/face protection]
		Any NIOSH-certified continuous flow supplied-air respirator equipped with a tight-fitting facepiece (half or full facepiece). [full facepiece provides eye/face protection]
		Any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a tight-fitting facepiece (half or full facepiece). [full facepiece provides eye/face protection]
		Any NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a hood, helmet, or a full facepiece. [provides eye/face protection]
		If No Cartridge Service Life Testing has been Conducted:

Fold Factor/ Hazard Ratio Range	Assigned Protection Factor (APF)	Type of Respirator
		Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a full facepiece. [provides eye/face protection]
		Any NIOSH-certified continuous flow supplied-air respirator equipped with a tight-fitting facepiece (half or full facepiece). [If a concern exists for eye/skin exposure from the chemical, the half-mask option should not be included in the 5(e) Order or EPA action.]
		Any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a tight-fitting facepiece (half or full facepiece). [If a concern exists for eye/skin exposure from the chemical, the half-mask option should not be included in the 5(e) Order or EPA action.]
		Any NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a hood, helmet, or a full facepiece. [provides eye/face protection]
51 to 1,000	1,000	If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:
		Any NIOSH-certified powered air purifying full facepiece respirator equipped with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges. [provides eye/face protection].
		Any NIOSH-certified powered air-purifying respirator equipped with a hood or helmet and appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges <i>with evidence demonstrating protection level of 1,000 or greater</i> . [provides eye/face protection]. [See important note below].*
		Any NIOSH-certified continuous flow supplied-air respirator equipped with a full facepiece. [provides eye/face protection].
		Any NIOSH-certified continuous flow supplied-air respirator equipped with a hood or helmet <i>with evidence demonstrating protection level of 1,000 or greater</i> . [provides eye/face protection]. [See important note below].*
		Any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a full facepiece. [provides eye/face protection].
		If No Cartridge Service Life Testing has been Conducted:
		Any NIOSH-certified continuous flow supplied-air respirator equipped with a full facepiece. [provides eye/face protection].
		Any NIOSH-certified continuous flow supplied-air respirator equipped with a hood or helmet <i>with evidence demonstrating protection level of 1,000 or</i>

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Fold Factor/ Hazard Ratio Range	Assigned Protection Factor (APF)	Type of Respirator
		greater. [provides eye/face protection]. [See important note below].* Any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a full facepiece. [provides eye/face protection].
1001 to 10,000	10,000	Any NIOSH-certified pressure-demand or other positive-pressure mode (e.g., open/closed circuit) self-contained breathing apparatus (SCBA) equipped with a hood or helmet or a full facepiece. [provides eye/face protection]

^{*} OSHA has assigned APFs of 1000 for certain types of hoods and helmets with powered air purifying respirators (PAPRs) or supplied air respirators (SARs) where the manufacturer can demonstrate adequate air flows to maintain positive pressure inside the hood or helmet in normal working conditions. However, the employer must have evidence provided by the respirator manufacturer that the testing of these respirators demonstrates performance at a level of protection of 1,000 or greater to receive an APF of 1,000. This level of performance can best be demonstrated by performing a Workplace Protection Factor (WPF) or Simulated Workplace Protection Factor (SWPF) study or equivalent testing. Without testing data that demonstrates a level of protection of 1,000 or greater, all PAPRs and SARs with helmets/hoods are to be treated as loose-fitting facepiece respirators, and receive an APF of 25.

TABLE III. COMBINATION PARTICULATE/AEROSOL AND GAS/VAPOR RESPIRATORS

Fold Factor/ Hazard Ratio Range	Assigned protection factor	Type of Respirator
2 to 10	10	If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:
		Any NIOSH-certified air-purifying half-mask respirator equipped with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges in combination with N100 (if oil aerosols absent), R100, or P100 filters or an appropriate canister incorporating N100 (if oil aerosols absent), R100, or P100 filters. [If a concern exists for eye/skin exposure from the chemical, the half-mask option should not be included in the 5(e) Order or EPA action.]
		Any NIOSH-certified powered air-purifying respirator with a hood or helmet and with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges in combination with HEPA filters. [provides eye/face protection]
		Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a half-mask. [If a concern exists for eye/skin exposure from the chemical, the half-mask option should not be included in the 5(e) Order or EPA action.]
		Any NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece, hood, or helmet. [provides eye/face protection]
		Any NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a half-mask. [If a concern exists for eye/skin exposure from the chemical, the half-mask option should not be included in the 5(e) Order or EPA action.]
		If No Cartridge Service Life Testing has been Conducted:
		Any NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece, hood, or helmet. [provides eye/face protection]
		Any NIOSH-certified negative pressure (demand) supplied-air respirator (half-mask or full facepiece). [If a concern exists for eye/skin exposure from the chemical, the half-mask option should not be included in the 5(e) Order or EPA action.]
	•	Any NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a half-mask. [If a concern exists for eye/skin exposure from the chemical, the half-mask option should not be included in the 5(e) Order or EPA action.]

Fold Factor/ Hazard Ratio Range	Assigned protection factor	Type of Respirator
11 to 25	25	If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:
		Any NIOSH-certified powered air-purifying respirator with a loose-fitting hood or helmet that is equipped with an appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridge in combination with HEPA filters. [provides eye/face protection]
		Any NIOSH-certified powered air-purifying respirator equipped with a loose fitting facepiece with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges in combination with HEPA filters. [provides eye/face protection]
		Any NIOSH-certified continuous flow supplied-air respirator equipped with a hood or helmet. [provides eye/face protection]
		Any NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece. [provides eye/face protection]
		If No Cartridge Service Life Testing has been Conducted:
		Any NIOSH-certified continuous flow supplied-air respirator equipped with a loose fitting facepiece, hood, or helmet. [provides eye/face protection]
		Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a full facepiece. [provides eye/face protection]
26 to 50	50	If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:
		Any NIOSH-certified air-purifying full facepiece respirator equipped with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges in combination with N100 (if oil aerosols absent), R100, or P100 filters or an appropriate canister incorporating N100 (if oil aerosols absent), R100, or P100 filters. [provides eye/face protection]
		Any NIOSH-certified powered air-purifying respirator with a tight-fitting facepiece (half or full facepiece) equipped with appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridges in combination with HEPA filters. [full facepiece provides eye/face protection]
		Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a full facepiece. [provides eye/face protection]
		Any NIOSH-certified continuous flow supplied-air respirator equipped with a tight-fitting facepiece (half or full facepiece). [full facepiece provides eye/face protection]
		Any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a tight-fitting facepiece (half or full facepiece). [full facepiece provides eye/face protection]

Fold Factor/ Hazard Ratio Range	Assigned protection factor	Type of Respirator
		Any NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a hood or helmet or a full facepiece. [provides eye/face protection]
		If No Cartridge Service Life Testing has been Conducted:
		Any NIOSH-certified negative pressure (demand) supplied-air respirator equipped with a full facepiece. [provides eye/face protection]
		Any NIOSH-certified continuous flow supplied-air respirator equipped with a tight-fitting facepiece (half or full facepiece). [full facepiece provides eye/face protection]
		Any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a tight-fitting facepiece (half or full facepiece). [full facepiece provides eye/face protection]
		Any NIOSH-certified negative pressure (demand) self-contained breathing apparatus (SCBA) equipped with a hood or helmet or a full facepiece. [provides eye/face protection]
51 to 1,000	1,000	If Data on Cartridge Service Life Testing has been Reviewed and Approved by EPA:
		Any NIOSH-certified powered air purifying fill facepiece respirator equipped with an appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridge in combination with HEPA filters. [provides eye/face protection].
		Any NIOSH-certified powered air-purifying respirator with a loose-fitting hood or helmet that is equipped with an appropriate gas/vapor (acid gas, organic vapor, or substance specific) cartridge in combination with HEPA filters with evidence demonstrating protection level of 1,000 or greater. [provides eye/face protection]. [See important note below].*
		Any NIOSH-certified continuous flow supplied-air respirator equipped with a full facepiece. [provides eye/face protection].
		Any NIOSH-certified continuous flow supplied-air respirator equipped with a hood or helmet <i>with evidence demonstrating protection level of 1,000 or greater</i> . [provides eye/face protection]. [See important note below].*
		Any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a full facepiece. [provides eye/face protection].
		If No Cartridge Service Life Testing has been Conducted:
		Any NIOSH-certified continuous flow supplied-air respirator equipped with a full facepiece. [provides eye/face protection].
		Any NIOSH-certified continuous flow supplied-air respirator equipped

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Fold Factor/ Hazard Ratio Range	Assigned protection factor	Type of Respirator
		with a hood or helmet with evidence demonstrating protection level of 1,000 or greater. [provides eye/face protection]. [See important note below].* Any NIOSH-certified pressure-demand or other positive pressure mode supplied-air respirator equipped with a full facepiece. [provides eye/face protection].
1001 to 10,000	10,000	Any NIOSH-certified pressure-demand or other positive-pressure mode (e.g., open/closed circuit) self-contained breathing apparatus (SCBA) equipped with a hood or helmet or a full facepiece. [provides eye/face protection]

^{*} OSHA has assigned APFs of 1000 for certain types of hoods and helmets with powered air purifying respirators (PAPRs) or supplied air respirators (SARs) where the manufacturer can demonstrate adequate air flows to maintain positive pressure inside the hood or helmet in normal working conditions. However, the employer must have evidence provided by the respirator manufacturer that the testing of these respirators demonstrates performance at a level of protection of 1,000 or greater to receive an APF of 1,000. This level of performance can best be demonstrated by performing a Workplace Protection Factor (WPF) or Simulated Workplace Protection Factor (SWPF) study or equivalent testing. Without testing data that demonstrates a level of protection of 1,000 or greater, all PAPRs and SARs with helmets/hoods are to be treated as loose-fitting facepiece respirators, and receive an APF of 25.

Appendix A: Risk Assessment and Calculation of Hazard Ratio

The calculated Margin of Exposure (MOE_C) for the PMN substance is the ratio of the No Observed Adverse Effect Level (NOAEL), normally obtained from animal toxicity studies, divided by the estimated exposure level (EEL):

$$MOE_C = NOAEL / EEL$$

If a NOAEL does not exist, the Lowest Observed Adverse Effect Level (LOAEL) can be used in calculating the MOE_C, where:

$$MOE_C = LOAEL / EEL.$$

The MOE_C is used with suitable guidelines to determine whether the exposure may cause human health effects. In the majority of cases, when the period of human exposure is comparable to the animal test exposure, an Acceptable MOE (MOE_A) greater than 100 for a NOAEL or greater than 1000 for a LOAEL will imply no adverse human health effects. For further discussion, see *Barnes and Dourson*, *Regulatory Toxicology and Pharmacology* 8:471-486, 1988.

The following calculation demonstrates the derivation of the margin of exposures ratio (MOE_A/MOE_C):

$$MOE_A/MOE_C = NOAEL/OEL * EEL/NOAEL = EEL/OEL NOAEL / EEL$$

The ratio of EEL over the Occupational Exposure Limit (OEL) is the equivalent of a hazard ratio. This hazard ratio is used to estimate the assigned protection factor (APF), which is the level of protection required to protect workers from the substance.

Appendix B: Additional Considerations for the Selection and Use of Respirators

Before a specific respirator from within any group is selected, it is important to evaluate the characteristics of the various respirators available and how they might be used in the work environment. An evaluation of these factors will help to ensure that the individual who is required to use the respirator is able to perform the work required in an effective and comfortable manner. Some of the factors to consider include:

Service life: What is the expected service time of the cartridge or filter that will be used? Will this

service life affect the ability of the individual to do the job effectively? Temperature and humidity conditions in the workplace may also affect the effectiveness of respirator

filters and cartridges.

Need for mobility: Limits for hoses may include length, entry, and exit points. Bulkiness may limit entry

into tight spaces. Airline respirators should not be used by mobile employees around

moving machinery to avoid entanglement of the respirator in the equipment.

Compatibility: Will the respirator be compatible with other protective equipment that must be worn?

For example, will it fit when used with other equipment such as safety glasses, a face

shield or welding equipment?1

Durability: Are there physical limitations for using a specific respirator, for example the need to

consider flammability for welding applications? Heavy work that is physically draining

may affect an employee's capability of wearing certain types of respirators.

Comfort factors: Does the respirator create uncomfortable working conditions for the worker? For

example, is high heat or humidity a factor? Employees wearing respirators for longer periods of time may need respirators that impose the minimum possible physical

burden.

Stressful activities: Will the worker be performing physically demanding work while wearing the

respirator? Heavy work that is physically draining may affect an employee's

capability to wear certain types of respirators.

Other factors: What is the weight, breathing resistance, and ease of use of the respirator? Does it

impair the worker's vision, hearing, communication, and physical movement necessary

to perform jobs safely?

While the EPA cannot evaluate these factors for individual workers and workplaces, the submitter should take these factors into account when determining which of the available respirator options to select. A suitably-trained respiratory protection program administrator or another competent person at the work site should select the most appropriate respirator from the list of respirators required by EPA.

¹ Eyeglass wearers must ensure that the spectacle temple bars do not interrupt the face to facepiece seal in a full facepiece respirator. For eyeglass wearers using full facepiece respirators, the options are to use eyeglasses that mount inside the facepiece (most respirator manufacturers can supply a spectacles kit for this purpose) or use contact lenses.

APPENDIX C: FIT TESTING

To obtain adequate respiratory protection, the respirator must fit the wearer correctly. Respirators that don't seal properly around the face offer only the illusion of protection. Fit testing is required for all negative or positive pressure *tight-fitting* facepiece respirators. The OSHA Respiratory Protection Standard (29 CFR 1910.134) requires that fit testing be performed before an employee first starts wearing a respirator in the work environment, whenever a different respirator facepiece is used, and at least annually thereafter.

Purpose: The primary purpose of fit testing is to identify the specific make, model, style, and size of respirator best suited for each employee. In addition, fit testing also provides an opportunity to check on problems with respirator wear, and reinforces respirator training by having wearers review the proper methods of donning and wearing the respirator.

Pre-Fit Test Procedures: Prior to the actual fit test, the employee must be shown how to put on a respirator, position it on the face, set strap tension, and determine an acceptable fit. Next, the employee must be allowed to choose a respirator from a sufficient number of models and sizes so that the employee can find an acceptable and correctly fitting respirator. Once an acceptable respirator has been found -- which takes into account the position of the mask on the face, nose, and cheeks; room for eye protection; and room to talk -- a user seal check must be conducted (refer to on "Use of Respirators"). To accommodate the variability of face size characteristics among individuals, a number of manufacturers offer facepieces in several sizes and models.

Types of Fit Testing: Fit testing may either be *qualitative (QLFT)* or *quantitative (QNFT)*, and must be administered using an OSHA-accepted QLFT or QNFT protocol. These protocols are described in mandatory Appendix A to 1910.134. Prior to the commencement of the fit test, the employee must be given a description of the fit test and a description of the exercises that he or she will be performing during fit testing. The respirator to be tested must be worn for at least five minutes before the start of the fit test. The employee must be fit tested with the same make, model, style, and size of respirator that will be used in the workplace.

Qualitative fit testing (QLFT). Qualitative fit testing involves the introduction of a gas, vapor, or aerosol test agent into an area around the head of the respirator user. A determination is then made as to whether or not the wearer can detect the presence of the test agent through means such as odor, taste, or nasal irritation. If the presence of the test agent is detected inside the mask, the respirator fit is considered to be inadequate.

There are four qualitative fit test protocols approved in OSHA's standard. The isoamyl acetate (IAA) test determines whether a respirator is protecting a user by questioning whether the user can smell the distinctive odor of IAA. Both the saccharin and BitrexTM tests involve substances with distinctive tastes that should not be detected through an effective respirator. The irritant smoke (e.g., stannic chloride) test involves a substance that elicits an involuntary irritation response in those exposed to it.

Before conducting a qualitative test, the worker must undergo a sensitivity test to determine if he or she can taste, smell or react to the substance. When performing the isoamyl acetate test, the protocol requires that separate rooms be used for the odor screening and fit tests, and that the rooms be sufficiently ventilated to ensure that there is no detectable odor of IAA prior to a test being conducted. This will prevent olfactory fatigue among workers being fit tested by preventing a buildup of IAA in the general room air.

Quantitative fit testing (QNFT). In a quantitative fit test, the adequacy of respirator fit is assessed by numerically measuring the amount of leakage into the respirator. This testing can be done by either generating a test aerosol as a test atmosphere, using ambient aerosol as the test agent, or using controlled negative pressure (CNP) to measure the volumetric leak rate. Appropriate instrumentation is required to quantify respirator fit.

Appendix D: The Role of OSHA and NIOSH in Respiratory Protection

The OSHA Respiratory Protection Standard

The Occupational Safety and Health Administration's (OSHA's) Respiratory Protection Standard (29 CFR 1910.134) which became effective on October 5, 1998, updated and replaced a standard that OSHA had adopted in 1971. OSHA revised it 1998 Respiratory Protection Standard in August 2006 to add APFs and Maximum Use Concentrations (MUCs). The Respiratory Protection Standard requires employers to establish and maintain a respiratory protection program to protect their respirator-wearing workers. It specifies only the minimum requirements for an effective respiratory protection program; employers are encouraged to exceed these minimum criteria if doing so enhances the safety and health of their employees. The major requirements of a respiratory protection program, as outlined in OSHA's Respiratory Protection Standard, are:

- 1) A written respiratory protection program document with specific procedures that tailor the program to the individual worksite including assignment of individual responsibility, accountability, and authority for required activities of the respiratory protection program.
- 2) Completion of a hazard evaluation that characterizes respiratory hazards and conditions of work to assist employers in selecting appropriate respirators.
- 3) Selection of a NIOSH-certified respirator based upon the hazard evaluation and the development of cartridge change-out schedules, if applicable.
- 4) A medical evaluation to determine the ability of workers to wear the respirator selected.
- 5) Annual qualitative or quantitative fit testing of tight-fitting respirators to minimize faceseal leakage and ensure that the respirators provide adequate protection.
- 6) Annual training of employees on respirator selection, use, maintenance and care.

The Role of NIOSH in Respiratory Protection

The National Institute for Occupational Safety and Health (NIOSH), under the authorization of the Federal Mine Safety and Health Act of 1977 and the Occupational Safety and Health Act of 1970, provides a testing, approval, and certification program assuring commercial availability of safe personal protective devices and reliable industrial hazard measuring instruments. In addition to certifying respirators, NIOSH issues recommendations for respirator use and develops appropriate standards and test procedures for respiratory devices used to protect workers in hazardous environments. Industrial type respirator approvals are in accordance to the NIOSH federal respiratory regulations at 42 CFR Part 84 and development of respirator standards are in concert with various partners from government and industry. All NIOSH-certified respirators bear a "TC number" located on the respirator, packaging, or written material that comes with the respirator.

In June 1995, NIOSH updated and modernized the Federal regulation for certifying air-purifying particulate respirators [42 CFR Part 84]. The old Part 11 respirator certification regulation [30 CFR 11] was promulgated in 1972. On July 10, 1995, 30 CFR 11 was replaced by 42 CFR Part 84. Only certifications of nonpowered, air-purifying, particulate-filter respirators were affected by this change from Part 11 to Part 84. Certification requirements and classes for all other types of respirators and components (including chemical cartridges, self-contained breathing apparatus (SCBA), airlines, and powered air purifying respirators) were moved to 42 CFR 84 without change.

In 1987, NIOSH published the NIOSH Respirator Decision Logic (RDL). Since then NIOSH has revised its respirator certification standard (42 CFR 84 on June 8, 1995). In October 2004, NIOSH released its updated respirator selection guidance, the Respirator Selection Logic (RSL). The purpose of the RSL is to provide guidance to respirator program administrators on respirator selection that incorporates the changes necessitated by the revisions to the respirator use and certification regulations and changes in NIOSH policy. In addition, NIOSH revised its carcinogen policy to recommend the complete range of respirators for those carcinogens with quantitative recommended exposure limits (RELs).

Although the APFs used in the RSL are based on the 1987 NIOSH Respirator Decision Logic, these APFs are generally consistent with current APFs being enforced by OSHA for respirator use.

Appendix E: NIOSH Certification Requirements for Particulate Respirators

For non-powered, air-purifying, particulate filter respirators, the new requirements in Part 84 include the creation of nine new classes of particulate filters. Typically, the new respirator category number for non-powered air-purifying respirators (84A) will apply to both the respirator facepiece and the cartridges, but note that the same facepiece may be certified under both the particulate and chemical certification categories (84A and 23C) for use with either particulate or chemical cartridges.

The new 84A cartridge classes are distinguished by filter efficiency and oil resistance of the filter. Three filter efficiency classes are specified in Part 84, including 95%, 99%, and 99.97% (100%). Since the NIOSH efficiency tests are conducted under worst-case conditions, (i.e., using the most penetrating particle size of 0.3 micrometer, a high airflow/breathing rate, a highly filter-degrading test aerosol, and charge-neutral particles) the efficiency of certified filters will be typically be higher than the approval or percentage number may indicate. For particles over one micrometer in size, all three filter categories are likely to provide close to 100% efficiency in particle removal. However, if the particle size of the chemical or contaminant is not known, the most protective level of filter efficiency should be selected.

There are also three oil resistance classes: N ($\underline{\mathbf{n}}$ ot oil resistant), R (oil $\underline{\mathbf{r}}$ esistant), and P (oil $\underline{\mathbf{p}}$ roof). The nine new particulate filter categories therefore include:

- N95, N99, and N100 for use in environments with no oil mist;
- R95, R99, and R100 for use in environments where some oil particles are present but the filters will be used for only one 8-hour workshift; and
- P95, P99, and P100 for environments where oil particles are present and the filters will be used for multiple work shifts according to an appropriate cartridge change-out schedule.

Note: High efficiency particulate air (HEPA) filters (equivalent to a filter efficiency of 99.97%) are still available for use with powered air-purifying respirators and will still be labeled "HEPA". HEPA filters are the only particulate filters that are approved for use with powered air-purifying respirators. A HEPA filter is equivalent to a N100, R100, or P100 filter.

APPENDIX F: GLOSSARY

Aerosol: liquid droplets or solid particles dispersed in a gas, that are of fine enough particle size (0.1 to 100 micrometers) to remain so dispersed for a period of time.

Air-purifying respirator: a respirator for which ambient air is passed through an air-purifying element that removes the contaminants. Air is passed through the air-purifying element by means of the human breathing action or by a blower.

Assigned protection factor: the expected workplace level of respiratory protection which would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users that are included in an effective respiratory protection program.

Cartridge: a container with a filter, sorbent, or catalyst, or combination of these items, which removes specific contaminants from the air that is passed through the container.

Cartridge service life: the period of time that a respirator, filter, or sorbent, or other respiratory equipment provides adequate protection to the wearer.

Dust: particles that are formed or generated from solid organic or inorganic materials by reducing their size through mechanical processes such as crushing, grinding, drilling, abrading, or blasting.

Employee exposure: exposure to a concentration of an airborne contaminant that would occur if the employee were not using respiratory protection.

Fume: particles formed when a volatilized solid, such as a metal, condenses in cool air. This physical change is often accompanied by a chemical reaction, such as oxidation. A fume can also be formed when a material such as magnesium metal is burned or when welding or gas cutting is done on galvanized metal.

Gas: a substance which is in the gaseous state at normal temperature and pressure.

Helmet: a rigid respiratory inlet covering that also provides head protection against impact and penetration.

High efficiency particulate air (HEPA) filter: a filter that is at least 99.97% efficient in removing monodisperse particles of 0.3 micrometers in diameter. The equivalent NIOSH 42 CFR 84 particulate filters are the N100, R100, and P100 filters.

Hood: a respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso. It is supplied with incoming respirable air for the wearer to breathe.

Immediately dangerous to life or health (IDLH): an atmosphere that poses an immediate threat to life, would cause irreversible adverse health effects, or would impair an individual's ability to escape from a dangerous atmosphere.

Loose-fitting facepiece: a respiratory inlet covering that is designed to form a partial seal with the face.

Mist: suspended liquid droplets generated by condensation from the gaseous to the liquid state or by breaking up a liquid into a dispersed state such as by splashing, foaming, or atomizing.

Negative pressure (demand) respirator: an atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation. This is the same mechanism as the one used in SCUBA (diving) gear.

Oxygen deficient atmosphere: an atmosphere which contains an oxygen partial pressure of less than 148 millimeters of mercury (19.5% by volume at sea level).

Particulate: solid or liquid matter that is dispersed in a gas, or insoluble solid matter dispersed in a liquid, so as to produce a heterogenous mixture.

Positive pressure respirator: a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

Powered air-purifying respirator: an air-purifying respirator that uses a blower to force ambient air through air-purifying elements to the inlet covering. It is a device equipped with a facepiece, hood, or helmet, breathing tube, canister, cartridge, filter, canister with filter, or cartridge with filter, and a blower.

Pressure demand respirator: a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

Respirator: any device designed to provide the wearer with respiratory protection against inhalation of a hazardous atmosphere.

Respiratory inlet covering: that portion of a respirator that forms the protective barrier between the user's respiratory tract and an air-purifying device or breathing air source, or both. It may be a facepiece, helmet, hood, suit, or a mouthpiece respirator with a nose clamp.

Self-contained breathing apparatus (SCBA): an atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

Supplied-air respirator (SAR) or airline respirator: an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

Tight-fitting (negative-pressure) respirator: a respirator in which the facepiece forms a complete seal with the face, and the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

Vapor: the gaseous state of a substance that is solid or liquid at normal temperature and pressure.

Appendix G: References and Sources of Additional Information

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